

REMARKS***Status of the claims:***

Claims 1-13 and claims 15-60 are pending. Claim 14 has been cancelled herein without prejudice or disclaimer. Applicants reserve the right to pursue the subject matter of cancelled claim 14 in continuing or divisional applications.

At item 3 of the Office Action mailed June 10, 2005, the Examiner indicated that the status identifier of claim 18 was incorrectly shown as "Currently Amended." Applicants checked claim 18 as presented February 23, 2004 as compared to claim 18 as first presented on January 27, 2003 to make sure that no claim amendments had been made that Applicants failed to show in their February 23, 2004 filing. In doing so, Applicants found that there were changes in the February 23, 2004 version of claim 18 as compared to the January 27 version of claim 18. Applicants reproduce claim 18 as it should have been presented in the February 23, 2004 filing below:

18. (Currently Amended) A process for diagnosing a susceptibility to cancer comprising:

~~determining from assaying~~ a sample derived from a human patient ~~to determine a~~ mutation in a human mismatch repair gene, said human mismatch repair gene comprising the polynucleotide sequence of claim 6.

Since no amendment to claim 18 was made in the present response, the status identifier of claim 18 is listed herein as "Previously Presented."

Also, because of this discrepancy, Applicants carefully checked the claims as presented in the February 23, 2004 amendment and discovered three other errors. Claims 1, 3 and 13 were each identified as "Original" claims, where in fact, each of these claims had an amendment changing the original recitation of "SEQ ID NO:2" to "SEQ ID NO:4." Therefore the proper status identifier of claims 1, 3, and 13 should have been "Currently Amended" in the February 23, 2004 filing. Applicants have used the status identifier "Previously Presented" for claims 1, 3, and 13 in the listing of claims presented herein.

Applicants apologize for the errors in the February 23, 2004 listing of claims. If the Examiner requires clarification or some alternate action on the part of the Applicants, please do not hesitate to contact Applicants' representative, listed below.

Provisional Election

The Examiner has required an election under 35 U.S.C. §121 of one of Groups I-X.

In order to be fully responsive, Applicants hereby provisionally elect, *with traverse*, the subject matter of Group V, represented by claim 14 (cancelled herein), and claims 22-34, 37-54, 56-60. Applicants reserve the right to file one or more divisional applications directed to the non-elected groups.

Additionally, Applicants note that the sequence of the cDNA contained in ATCC Deposit No. 75649 is related to the sequences of SEQ ID NO:1 and 2. The only reference to the sequence of the cDNA contained in ATCC Deposit No. 75649 made in the Requirement for Restriction is in Group VII, in which it is grouped with the cDNA contained in ATCC Deposit No. 75651 (which is related to the to the sequences of SEQ ID NO:3 and 4). Thus, it is unclear if the sequences of

- the cDNA contained in ATCC Deposit No. 75649,
- the protein encoded by the cDNA contained in ATCC Deposit No. 75649,
- SEQ ID NO:1 and
- SEQ ID NO:2

(hereafter "hMLH1 sequences") are intended to have been restricted out from the sequences of

- the cDNA contained in ATCC Deposit No. 75651,
- the protein encoded by the cDNA contained in ATCC Deposit No. 75651,
- SEQ ID NO:3 and
- SEQ ID NO:4

(hereafter "hMLH2 sequences"). Applicant would appreciate clarification on this matter. For the purposes of this election, however, Applicants assume that elected Group V encompasses an antibody that specifically binds hMLH2 proteins (as represented, for example by the protein of SEQ ID NO:4 and the protein encoded by the cDNA contained in ATCC Deposit No. 75651) and not hMLH1 proteins (e.g., the protein of SEQ ID NO:2 or the protein encoded by the cDNA contained in ATCC Deposit No. 75649.)

and not hMLH1 proteins (e.g., the protein of SEQ ID NO:2 or the protein encoded by the cDNA contained in ATCC Deposit No. 75649.)

Moreover, Applicants respectfully traverse the restriction requirement, at least as it applies to Groups directed to inventions reciting hMLH2 sequences - ostensibly, Groups I, III, V, VII (in part) and IX.

As a threshold matter, Applicants point out that M.P.E.P. § 803 lists the criteria for a proper restriction requirement:

Under the statute an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent (MPEP § 806.04 - § 806.04(i)) or distinct (MPEP § 806.05 - § 806.05(i)). If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions

Thus, even assuming, *arguendo*, that the Groups I, III, V, VII and IX, each as related to hMLH2 sequences, represented distinct or independent inventions, restriction remains improper unless it can be shown that the search and examination of both groups would entail a "serious burden." See M.P.E.P. § 803. Applicants submit that a search of the elected group of claims directed to antibodies that specifically bind the hMLH2 protein of the invention could hardly be performed without searching the hMLH2 protein itself, a search that would clearly provide useful information for the remaining groups. For example, the search for publications which disclose the hMLH2 polypeptides would lead the Examiner to references which disclose not only the polypeptides of Group III, but also (1) polynucleotide sequences encoding them, which would be relevant to evaluation of the claims of Groups I and VII; 2) antibodies that bind polypeptides, which would be relevant to evaluation of the claims of Group V; and/or 3) methods of using the aforementioned polynucleotides, polypeptides, and/or antibodies, which would be relevant to evaluation of the claims of Groups I and IX. Applicants submit that it would not be a serious burden to examine all the claims of Groups I, III, V, VII and IX, each as related to hMLH2 sequences, together.

Applicants respectfully request that the present restriction requirement be withdrawn upon consideration of the above arguments and in view of M.P.E.P. § 803.

Request for Rejoinder

The Examiner required restriction between the product claims of Groups V and the process claims of Group IX. In accordance with the decisions in *In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) and *In re Brouwer*, 77 F.3d 422, 37 USPQ 2d 1663 (Fed. Cir. 1996), and the notice published in the Official Gazette on March 26, 1996 setting forth new guidelines for the treatment of restricted product and process claims (*See* 1184 OG 86), Applicants respectfully request that if the restriction requirement is made final and if the claims of Group V (claims 22-34, 37-54 and 56-50) are found allowable, that the claim of Group IX (claims 35, 36 and 55) be rejoined and examined for patentability. *See* also M.P.E.P. § 821.04.

CONCLUSION

Applicants respectfully request that the amendments and remarks above be entered and made of record in the file history of the instant application. Should any fees additional to those listed on the Fee Transmittal Sheet be deemed necessary, please charge such fees to Deposit Account No. 08-3425.

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Respectfully submitted,

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